

**Appl. No.** : 10/621,196  
**Filed** : July 15, 2003

### **AMENDMENTS TO THE DRAWINGS**

Replacement sheets for Figures 1B, 1C, 2, 3, 4, 7, 8, 9, 13C, 16, 17A and 23 are provided herewith.

The replacement sheets for Figures 1B, 7, 8, 9, 13C, 16, 17A and 23 include amendments to conform the figures to the specification.

The replacement sheets for Figures 1C, 2, 3, and 4 contain no amendments and are merely provided herewith as clean copies of the figures..

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## SUMMARY OF INTERVIEW

### Exhibits and/or Demonstrations

None

### Identification of Claims Discussed

Claims 6, 16, 31, and 39 were discussed.

### Identification of Prior Art Discussed

The following U.S. Patent and publications were discussed: US 5,808,665; US 6,148,823; and US 2001/0021805.

### Proposed Amendments

Applicant agreed to amend Claims 1, 31 and 39 to clarify the claims.

### Principal Arguments and Other Matters

Applicants argued that the prior art reference listed above do not teach or suggest the claimed invention.

### Results of Interview

Applicant agreed to file a detailed response with clarifying amendments to Claims 1, 31, and 39.

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### REMARKS

The foregoing amendments are responsive to the February 22, 2006 Office Action. Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the following remarks.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

#### Response to Objections to the Drawings

Fig. 1A has been amended to show the temperature and magnetic field sensors at the distal end of the tool. The amended drawing discloses no new matter (see paragraph 21, lines 3-4).

Fig. 13C has been amended to show the power supply as reference number 916. The reference in paragraph 128 to the power supply of Fig. 13C has been amended accordingly.

Figs. 1A, 1B, and 1C have been amended to show that systems depicted in each of those figures is identified by the number 700.

The Examiner objected to unspecified drawings on the grounds that they are partially hand drawn. The Examiner is reminded that “[t]he Office no longer considers drawings as formal or informal. . . . Examiners should review the drawings for disclosure of the claimed invention and for proper use of reference numerals.” M.P.E.P. 608.02(b). Cleaner copies of Figs. 1C, 2, 3, and 4 are provided herewith. As for other hand-drawn figures and references, Applicant respectfully submits that they are “readable and reproducible for publication purposes” and therefore sufficient. M.P.E.P. 608.02(b).

Applicant has amended Figures 7, 8, and 9 to correct the reference numerals 317, 318, 316, and 319 to 307, 308, 306, and 309, respectively, in to conform with the specification.

Figs. 16, 17A, and 23 have been amended to account for the Examiner’s objections.

These amendments add no new matter.

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#### Response to Objections to the Specification

The abstract of the disclosure has been amended to contain fewer than 150 words. Appropriate amendments have been made to the specification in response to the Examiner's objections.

These revisions add no new matter.

#### Response to Objection to Title of Invention

The Examiner objected to the title of the invention because it was "not sufficiently descriptive." But, there is no requirement that the title be "sufficiently descriptive." The Examiner may object to the title of the invention only if it is "not descriptive." M.P.E.P. § 606.01. To be descriptive, the title need only "serve to describe." *Merriam-Webster Online Dictionary*, <http://www.m-w.com/dictionary/descriptive>. The title "Apparatus and Method for Catheter Guidance Control and Imaging" serves to describe the invention. Therefore, it is descriptive and appropriate.

Applicant requests the Examiner to withdraw the objection to the title.

#### Response to Rejection of Claims 1-20 and 31-50 Under 35 U.S.C. 112, second paragraph

The Examiner rejected claims 1-20 and 31-50 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner objected to the term "catheter-like" in Claims 1 and 39 because the metes and bounds of the term could not be determined. The metes and bounds of "catheter-like" are readily ascertained from the term itself, the specification, and the nature of the invention. The term refers not just to catheters, but to all "catheter-like" tools. As noted in paragraph 70, to be catheter-like, the tool must have a distal end. The claims recite a tool that is inserted into the body of the patient. A catheter is meant to be inserted into the body of a patient. Thus, a "catheter-like" tool is also meant to be inserted into the body of a patient.

#### Response to Rejection of Claims 1, 5-8, 11, 19, 39 and 42 Under 35 U.S.C. 102(e)

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The Examiner rejected Claims 1, 5-8, 11, 19, 39 and 42 under 35 U.S.C. 102(e) as being anticipated by U.S. 2001/0021805 to Blume et. al, ("Blume").

In Blume, a moveable magnet is mechanically manipulated to produce a desired field. Blume does not teach or suggest first and second electromagnet clusters. Moreover, Blume does not teach or suggest computing a difference between a desired position and a current position.

Regarding Claim 1, the cited prior art does not teach or suggest a magnetic field source for generating a magnetic field outside the body, the magnetic source comprising a first cluster of first electromagnets disposed substantially above the patient, wherein at least one pole of each of the first electromagnets is provided to a first common magnetic circuit, the magnetic source further comprising a second cluster of second electromagnets disposed substantially below the patient, wherein at least one pole of each of the second electromagnets is provided to a second common magnetic circuit, wherein the second cluster is substantially opposed to the first cluster and wherein the first common magnetic circuit is provided to the second common magnetic circuit through a third magnetic circuit, a tool having a distal end responsive to the magnetic field, one or more magnetic sensors to sense an present position of the distal end by sensing a magnetic field produced by the distal end, and a system controller for controlling the magnetic field source to provide a position and command input to control a movement of the distal end, the system controller configured to compute a difference between a desired position of the distal end and the present position of the distal end, the position and command input computed using feedback using at least the present position, the desired position, and a previous position input, the position and command input comprising electric current magnitudes and corresponding electric current polarities for a plurality of electromagnets.

Regarding Claims 6, 7, and 8, Blume does not teach or suggest a servo system inherently comprising an input related to dynamic position of an organ. "In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by

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probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Examiner states that Blume et al. is inherently capable “when appropriately programmed” of compensating for a dynamic position of an organ, as recited in Claim 6. But, the Examiner provides no basis in fact or technical reasoning that “appropriate programming” is an “inherent characteristic” of Blume et al. that “necessarily flows from the teachings of the applied prior art.” There is no indication that the servo system mentioned in Blume et al. utilizes a feedback mechanism at all, much less that it uses a feedback mechanism that compensates for a dynamic position of an organ.

Regarding Claim 11, the cited prior art does not teach or suggest the elements of Claim 1, further comprising an X-axis controller and amplifier, a Y-axis controller and amplifier, and a Z-axis controller and amplifier.

Regarding Claim 19, the cited prior art does not teach or suggest the apparatus of Claim 14, wherein the system controller is configured to calculate a position error of said distal end using data from the magnetic sensor and to control said magnetic field source to correct the position error. Again, the mere contention that Blume et al. is capable of being programmed to calculate a position error is, without more, insufficient to make out a showing of inherency.

Regarding Claim 39, the cited prior art does not teach or suggest an apparatus for controlling the movement of a catheter-like tool to be inserted into the body of a patient, comprising a controllable magnetic fields source having first and second clusters of poles substantially opposed to one another, a tool having a distal end responsive to said magnetic field, and one or more magnetic sensors to sense a magnetic field produced by said distal end. Like Claim 1, Claim 39 recites a magnetic sensor to sense a magnetic field produced by the distal end of the tool. The sensors in Blume et al. do not sense a magnetic field produced by the distal end of the tool. Regarding Claim 42, the cited prior art does not teach or suggest the elements of Claim 39, further comprising an operator interface unit.

Accordingly, Applicant asserts that Claims 1, 5-8, 11, 19, 39, and 42 are allowable over the prior art, and Applicant requests allowance of Claims 1, 5-8, 11, 19, 39, and 42.



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Response to Rejection of Claim 31 Under 35 U.S.C. 103(a)

The Examiner rejected Claim 31 under 35 U.S.C. 103(a) as being unpatentable over Hastings (U.S. 6,148,823) in view of Colley et al. (U.S. 4,354,501).

Hastings teaches mechanically manipulating a conventional "C" magnet having two poles. Hastings does not teach or suggest first and second clusters of poles. Colley teaches an ultrasonic catheter for to detect air emboli. Colley does not teach or suggest using ultrasonics to locate a catheter tip.

Regarding Claim 31, the cited prior art does not teach or suggest a magnet source for generating a magnetic field, said magnetic source comprising a first cluster of first electromagnets, wherein at least one pole of each of said first electromagnets is provided to a first common magnetic circuit, said magnetic source further comprising a second cluster of second electromagnets, wherein at least one pole of each of said second electromagnets is provided to a second common magnetic circuit, wherein said second cluster is substantially opposed to said first cluster and wherein said first common magnetic circuit is provided to said second common magnetic circuit through a third magnetic circuit, a tool having a distal end responsive to said magnetic field, one or more piezoelectric rings disposed about said distal end, and a system controller configured to locate said distal end based at least in part of ultrasonic radiation from said piezoelectric rings, said system controller further configured to regulate said magnetic field to provide a position and command input to control said tool distal end position.

Response to Rejection of Claim 2 Under 35 U.S.C. 103(a)

The Examiner rejected Claim 2 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. 2001/0021805) in view of Galel (U.S. 5,492,131). The cited prior art does not teach or suggest the elements of Claim 1, with the system controller of Claim 1 comprising a closed-loop feedback servo system. For example, Galel does not teach or suggest first and second magnet clusters or a controller configured to compute a difference between a desired position of the distal end and the present position of the distal end, the position and command input computed using feedback using at least the present position, the desired position, and a previous position input, the position and command input comprising electric current magnitudes and corresponding electric current polarities for a plurality of electromagnets.

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Response to Rejection of Claim 32 Under 35 U.S.C. 103(a)

The Examiner rejected Claim 32 under 35 U.S.C. 103(a) as being unpatentable over Hastings (U.S. 6,148,823) as modified by Colley et al. (U.S. 4,354,501) as applied to Claim 31.

Hastings teaches mechanically manipulating a conventional "C" magnet having two poles. Hastings does not teach or suggest first and second clusters of poles. Colley teaches an ultrasonic catheter for to detect air emboli. Colley does not teach or suggest using ultrasonics to locate a catheter tip.

The cited prior art does not teach or suggest the apparatus of Claim 31, further comprising a closed servo loop system that receives position and command input from the system controller to regulate the magnetic force regulate magnetic force magnetic direction and magnetic field gradients by controlling currents in said first cluster of first electromagnets and said second cluster of said second electromagnets.

Response to Rejection of Claims 4 and 41 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 4 and 41 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. 2001/0021805) in view of Abela et al. (U.S. 5,769,843).

Regarding Claim 4, the cited prior art neither teaches nor suggests the elements of Claim 1, with the distal end comprising one or more ultrasound emitters.

Regarding Claim 41, the cited prior art neither teaches nor suggests the apparatus of Claim 39, with the distal end comprising one or more ultrasound emitters for providing sensor data to a system controller.

Response to Rejection of Claims 3, 12, 13, 40, 46 and 47 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 3, 12, 40, 46 and 47 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. 2001/0021805) as modified by Abela et al. (U.S. 5,769,843) as applied to Claims 4 and 41, and further in view of Kubota et al. (U.S. 2001/0004215).

Regarding Claim 3, the cited prior art neither teaches nor suggests the apparatus of Claim 1, having or more magnetic sensors and one or more temperature sensors. There is no suggestion to combine Blume et al. as modified by Abela et al. with Kubota et al. Blume et al. and Abela et



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al. both relate to medical instruments. Kubota et al. relates to a throttle valve in the intake manifold of an internal combustion engine. There is no hint in Blume et al. or Abela et al. to inspect internal combustion engine art for technical ideas. Nor is there any suggestion in Kubota et al. that its innovations in the internal combustion engine art ought to be applied to medical devices.

Regarding Claim 12, the cited prior art neither teaches nor suggests the apparatus of Claim 1, further comprising a communication controller, a calibration fixture, and one or more temperature sensors.

Regarding Claim 13, the cited prior art neither teaches nor suggests the apparatus of Claim 12, wherein the temperature sensors are paired with magnetic sensors.

Regarding Claim 40, the cited prior art neither teaches nor suggests the apparatus of Claim 39, wherein the distal end comprises one or more magnetic sensors and one or more temperature sensors.

Regarding Claim 46, the cited prior art neither teaches nor suggests the apparatus of Claim 39, further comprising a communication controller, a calibration fixture, and one or more temperature sensors.

Regarding Claim 47, the cited prior art neither teaches nor suggests the apparatus of Claim 39, wherein the temperature sensors are paired with magnetic sensors.

#### Response to Rejection of Claims 33-37 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 33-37 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. 2001/0021805) as modified by Abela et al. (U.S. 5,769,843) and Kubota et al. (U.S. 2001/0004215) as applied to Claims 3, 12, 13, 40, 46 and 47, and further in view of Colley et al. (U.S. 4,354,501), Hastings (U.S. 6,148,823), and Galcl (U.S. 5,492,131).

Hastings teaches mechanically manipulating a conventional "C" magnet having two poles. Hastings does not teach or suggest first and second clusters of poles. Colley teaches an ultrasonic catheter for to detect air emboli. Colley does not teach or suggest using ultrasonics to locate a catheter tip.

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Thus, regarding Claim 33, the cited prior art does not teach or suggest the apparatus of Claim 32, further comprising a closed servo loop system that receives position and command input from a system controller to regulate magnetic force.

Regarding Claim 34, the cited prior art does not teach or suggest the apparatus of Claim 33, wherein the control system is configured to calculate respective torque and associated current for a magnetic source, to configure a magnetic field to move the distal end of a tool to a desired location.

Regarding Claim 35, the cited prior art does not teach or suggest the apparatus of Claim 34, wherein the closed-loop servo circuit includes a correction input that compensates for the dynamic position of a patient's organs.

Regarding Claim 36, the cited prior art does not teach or suggest the apparatus of Claim 35, wherein a correction input is generated by an auxiliary device that provides data concerning the dynamic position of an organ.

Regarding Claim 37, the cited prior art does not teach or suggest the apparatus of Claim 36, wherein the auxiliary device is one or more of an x-ray, ultrasound, or radar equipment forming a stereotactic frame of reference incorporating data relative to the frame of reference, dynamically moving in unison with body organs.

Response to Rejection of Claims 9, 10, 14, 15, 17, 44, 45, 48 and 50 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 9, 10, 14, 15, 17, 44, 45, 48 and 50 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. 2001/0021805) in view of Blume et al. (U.S. 6,014,580).

Regarding Claim 9, the cited prior art does not teach or suggest the apparatus of Claim 1, wherein the system controller includes a Virtual Tip control device that allows user control inputs.

Regarding Claim 10, the cited prior art does not teach or suggest the apparatus of Claim 1, further comprising a Virtual Tip and Calibration Fixture Controller and Virtual Tip assembly.

Regarding Claim 14, the cited prior art does not teach or suggest the apparatus of Claim 1, wherein the system controller coordinates operation of an X-Axis Controller, a Y-Axis Controller, and a Z-Axis Controller, and

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Regarding Claim 15, the cited prior art does not teach or suggest the apparatus of Claim 14, where the Virtual Tip provides tactile feedback to the operator.

Regarding Claim 17, the cited prior art does not teach or suggest the apparatus of Claim 14, where the system controller causes the distal end of the tool to follow the movements of the Virtual Tip.

Regarding Claim 44, the cited prior art does not teach or suggest the apparatus of Claim 39, further comprising a Virtual Tip control device to allow user control inputs.

Regarding Claim 45, the cited prior art does not teach or suggest the apparatus of Claim 39, further comprising a Virtual Tip and Calibration Fixture Controller and a Virtual Tip assembly.

Regarding Claim 48, the cited prior art does not teach or suggest the apparatus of Claim 39, further comprising a Virtual Tip that provides tactile feedback to the operator.

Regarding Claim 50, the cited prior art does not teach or suggest the apparatus of Claim 39, further comprising a system controller to control a magnetic field produced by the three-dimensional magnetic field source, to cause the distal end of the tool to follow the movements of a Virtual Tip.

#### Response to Rejection of Claim 38 Under 35 U.S.C. 103(a)

The Examiner rejected Claim 38 under 35 U.S.C. 103(a) as being unpatentable over Hastings (U.S. 6,148,823) as modified by Colley et al. (U.S. 4,354,501) as applied to Claim 31, and further in view of Blume et al. (U.S. 6,014,580).

Hastings teaches mechanically manipulating a conventional "C" magnet having two poles. Hastings does not teach or suggest first and second clusters of poles. Colley teaches an ultrasonic catheter for to detect air emboli. Colley does not teach or suggest using ultrasonics to locate a catheter tip.

Regarding Claim 38, the cited prior art does not teach or suggest the apparatus of Claim 31 including a virtual tip to control the movement of the distal end of a catheter.

#### Response to Rejection of Claims 16, 18, 20 and 49 Under 35 U.S.C. 103(a)

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The Examiner rejected Claims 16, 18, 20 and 49 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. 2001/0021805) as modified by Blume et al. (U.S. 6,014,580) as applied to Claims 9, 10, 14, 15, 17, 44, 45, 48 and 50, and further in view of Green (U.S. 5,808,665).

Green teaches tactile feedback based on pressure sensors at the end of a remotely-controlled instrument. Thus in Green the information for tactile feedback is obtained by direct measurement. Thus, Green requires specific sensors dedicated to measuring tactile feedback information. Green does not teach or suggest computing tactile feedback information according to a position error between an present position of the distal end of the tool and the desired position in a servo-feedback system.

Regarding Claim 16, the cited prior art does not teach or suggest the apparatus of Claim 14, where the Virtual Tip provides tactile feedback to an operator according to a position error between an present position of the distal end of the tool and the desired position of the distal end of the tool.

Regarding Claim 18, the cited prior art does not teach or suggest the apparatus of Claim 14, further comprising a Virtual Tip / Calibration Fixture Controller that receives encoder position, limit switch, and operator switch data from the Virtual Tip.

Regarding Claim 20, the cited prior art does not teach or suggest the apparatus of Claim 1, where the system controller initiates a tactile feedback response by providing feedback data to an operator control.

Regarding Claim 49, the cited prior art does not teach or suggest the apparatus of Claim 48, where the Virtual Tip provides tactile feedback according to a position error between the present position of the distal end and desired position of the distal end.

#### Response to Rejection of Claim 43 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 43 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. 2001/0021805) in view of Hastings (U.S. 6,148,823).

Blume is discussed above. Hastings teaches mechanically manipulating a conventional "C" magnet having two poles. Hastings does not teach or suggest first and second clusters of poles.

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Regarding Claim 43, the cited prior art does not teach or suggest the apparatus of Claim 39, where the first cluster of poles is connected to the second cluster of poles by a magnetic material.

Response to Provisional Rejection of Claims 1, 2, 5-9, 11, 14-17 and 20 Under Obviousness-Type Double Patenting

The Examiner provisionally rejected Claims 1, 2, 5-9, 11, 14-17 and 20 under the obviousness-type double patenting as being unpatentable over Claims 1, 2, 8-12, 14, 17-20 and 24 of copending Application No. 10/690,472.

Applicants will timely file a terminal disclaimer should the provisional rejection be sustained once agreement is reached on the claims.

Response to Provisional Rejection of Claims 1, 2, 6, 7, 9, 31 and 32 Under Obviousness-Type Double Patenting

The Examiner provisionally rejected Claims 1, 2, 6, 7, 9, 31 and 32 under the obviousness-type double patenting as being unpatentable over Claims 35, 36 and 42 of copending Application No. 10/690,472.

Applicants will timely file a terminal disclaimer should the provisional rejection be sustained once agreement is reached on the claims.


Summary

Applicant asserts that Claims 1-19 and 31-50 are in condition for allowance, and Applicant request allowance of Claims 1-19 and 31-50. If there are any remaining issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney at (949) 721-6305 or at the number listed below.

Respectfully submitted,

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Dated: July 27, 2006

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